

Standard wording for Participant Information and Consent Forms (PICFs)

Standard risk wording has been developed for various imaging procedures and procedures with risks for healthy volunteers. It is recommended to use this wording in the risk section of PICFs.

Imaging procedures

Risks of oral sedation – MRI (November 2020)

Statement for researchers

Undergoing an MRI requires remaining still in an enclosed space for an extended period. Completing an MRI can be difficult for people who experience anxiety or claustrophobia. Oral sedation is an option in these cases.

Risk wording

If you find completing an MRI difficult, taking an oral sedative may be an option. Your doctor will let you know if this is suitable for you. Oral sedation is very safe however, there are some risks involved. The risks are very rare. The most common risks are feeling dizzy or drowsy, temporary amnesia, unsteadiness and weakness. Less common reactions include rash, nausea and vomiting, change in appetite, disorientation, headache, sleep and vision disturbance, depression and agitation. Most patients do not have these problems. If these problems do happen, they occur soon after the sedation is taken and they usually get better very quickly. If you have any concerns about these risks, you should discuss them with the study team. Following sedation, you will need someone to drive you home.

Interventional Radiology investigation requiring heavy sedation/anaesthesia (November 2020)

Heavy sedation/anaesthesia is generally very safe however, there are some associated risks. The most common problems are feeling unwell or vomiting, bruising at the site of injections, sore throat or hoarse voice. Most patients do not have these problems. If these problems do happen, they usually get better very quickly. Damage to teeth may occur, but this is rare. The risk of brain damage or death due to heavy sedation/anaesthesia is very rare. The risk of problems from anaesthesia increases for patients who are having more major surgery, those with medical problems and those that require difficult anaesthetic procedures. If you have any concerns about these issues, you should discuss them with the study team. Following heavy sedation/anaesthesia, you will need someone to drive you home.

Risks of iodine based contrast - CT and angiography (June 2020)

The most common reported side effects are a warm feeling, metal taste in the mouth and pain at the injection site. There is also a low risk of side effects such as nausea, tingling and headaches. The risk of complications associated with the contrast dye is rare (less than 1%). Some of these risks are:

- An allergic reaction to the contrast dye. Such reactions usually are mild but may include rash, swelling, tightness in the throat or trouble breathing.
- A possibility for kidney damage if your kidneys are not functioning well. The function of your kidneys will be assessed via the blood testing performed as part of the screening process.

Dye extravasation (fluid flows outside the vessel) can occur which can cause other complications such as damage to tissues that come in contact with the dye.

Risks of gadolinium-based contrast – MRI (June 2020)

A rare but serious adverse reaction has been observed in patients that received a gadolinium-based contrast material during MRI examinations, a reaction called nephrogenic systemic fibrosis (NSF). Patients with kidney disease are at increased risk of developing NSF. NSF may cause skin thickening, joint pain and/or swelling. In rare cases NSF can lead to lung and heart problems and cause death. To minimize the likelihood that you will be affected, you may be required to have a blood test to measure your kidney function. If your blood test is abnormal, you will not be permitted to receive gadolinium unless specifically approved.

Procedure risks for healthy volunteers.**Liver Biopsy** (December 2020)

Liver biopsy is used [routinely*] to evaluate the extent and severity as well as the cause of your liver disease. The procedure may require up to a six hour stay in the hospital and involves first localising the liver under ultrasound and to mark the site on the skin where needle biopsy will be performed. Usually done under light sedation, the skin over the liver is then numbed with a local anaesthetic, followed by passing a small needle into the liver and removing a small sample of liver (1-2 cm long and a few mm in diameter). There is some pain associated with the procedure and usually right shoulder tip pain is experienced. In addition, about 20% of persons having a liver biopsy have some degree of pain over the liver that may last a few minutes to several hours. This occasionally requires pain medication. Other risks include inadvertent perforation of organs adjacent to the liver and bleeding from the biopsy site. Rarely significant internal bleeding may occur such that a blood transfusion, a radiological procedure to block the bleeding vessel, or even an open operation to sew up the hole in the liver is needed. These complications occur in less than 1 in 300 times with the risk of significant haemorrhage being around 1 in 1000 cases. Very rarely (fewer than 1 in 10,000 reported cases) death has occurred from bleeding after a liver biopsy.

* delete if not routine

Right Heart Catheter (December 2020)

After using local anaesthetic on the skin, a small tube (called a catheter) is placed through a needle in a vein in your arm, neck, or groin. The tube is directed towards the chambers of the right side of the heart, to the main artery feeding your lung or to the veins draining the heart or other organs (eg. the kidney, liver or brain). Moving the tube to different parts of the body is painless and you will generally be unaware of its location.

The risk of death or serious disability resulting from this procedure is extremely small. Amongst thousands of these research procedures performed at The Alfred, we are yet to encounter any serious problem leading to long term disability. There is a slight risk of damaging the vein or wall of the heart with the catheter causing internal bruising or bleeding. Generally this will quickly stop of its own accord and all that would be required is a period of observation. On very rare occasions (so rare that we have not encountered it) it might be necessary to repair the damage with an operation. It is not uncommon to experience some bleeding and bruising where the catheter was inserted in the arm or groin. This can generally be prevented by firm pressure over the area for at least 5 minutes and like other bruises it will resolve over the next week or so. The advancement of the catheter through the heart may cause an abnormal heart rhythm which may cause some thumping in your chest. This can be alleviated by removal of the catheter or by giving appropriate medication. Occasionally, rhythm disturbances may last a day or two, and require admission to hospital for a controlled shock to restore normal heart rhythm (cardioversion). Rarely, there could be blockage of the vein causing swelling of the relevant limb.

The whole procedure generally lasts 1-2 hours and it may be uncomfortable lying horizontally for this period.

Venepuncture (Taking Blood Samples) (December 2020)

Having a blood sample taken may cause some discomfort or bruising. Sometimes, the blood vessel may swell, or blood may clot in the blood vessel. Some people may feel faint when having blood taken, and may occasionally faint. Rarely, there could be bleeding or a minor infection. If this happens, it can be easily treated.